OK TO ENTER AM 11-19-99 Patent Patent Attorney's Docket No. 028723-060

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Joe GRAY et al

Application No.: 08/477,31

Filed: June 7, 1995

For: CHROMOSOME-SPECIFIC

STAINING TO DETECT

GENETIC REARRANGEMENTS
ASSOCIATED WITH CHROMOSOME

3 AND/OR CHROMOSOME 17

Group Art Unit: 1634

Examiner: A. Marschel

**REPLY** 

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

In complete response to the Official Action mailed March 17, 1999, Applicants offer the following remarks:

Claims 1, 48, and 50-58 are rejected under 35 U.S.C. §103(a) as purportedly obvious over U.S. Patent 4,710,465 to Weissman et al., taken in view of Lichter et al. (*PNAS* 85:9664-9668, 1988) and U.S. Patent 5,242,975 to Croce. This rejection is respectfully traversed.

The present application claims priority from U.S. Application Serial No. 06/819,314, filed January 16, 1986, and U.S. Application Serial No. 06/937,793, filed December 4, 1986. Both of these applications were filed before the publication of the Lichter et al. article in December, 1988, and before the filing of the Croce

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application on July 3, 1989. Accordingly, neither the Lichter publication nor the Croce Patent are properly cited as prior art against the present application. As the Examiner has conceded that the present claims are not *prima facie* obvious over the Weissman patent alone, Applicants maintain that a *prima facie* case of obviousness has not been made out.

However, the Examiner argues that the present claims are not supported by Applicants' 1986 priority applications, but only by Application Serial No. 07/382,793, filed July 19, 1989. Specifically, at page 3 of the Official Action, the Examiner asserts that the disclosure of the parent applications "lacks the specific citation of chromosomes 3 and 17 and particular functional embodiments and therefore priority is deemed to be lacking in said parents." However, Applicants maintain that support for the recitation that the genetic rearrangement is associated with chromosome 3 and/or chromosome 17 is implicit in the description that the staining reagents useful in the invention are specific to single chromosomes at page 11, lines 1-5 of Application Serial No. 06/937,793 and at page 10, lines 17-21 of Application Serial No. 06/819,314. One skilled in the art would understand the generic description of staining targeted chromosomal material to detect genetic rearrangements to describe each of the chromosomes, including chromosomes 3 and 17, as being the targeted material.

In view of the fact that support may be found in the instant application, which is identical to the series of applications from which priority is claimed as a divisional

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and continuation, and support may be found in the 06/937,793 and 06/819,314 applications filed in 1986 from which priority is claimed as a continuation-in-part, Lichter et al published in 1988 and Croce having a 1989 priority date and an issue date of 1993 are not proper prior art references. The combination of Lichter et al and Croce with Weissman is thus improper.

Furthermore, even if Lichter et al and Croce were prior art to the present application, the combination of these two publications with the Weissman publication *still* would not render the present claims *prima facie* obvious. The Examiner has cited the Croce patent for its alleged disclosure of "chromosome 3 and 17 translocation targets" (Official Action of June 30, 1998 at 3). Specifically, the Examiner points to col. 3, lines 4-21 of the Croce patent, presumably for its purported disclosure of chromosome 3 and 17 translocation targets. However, a careful reading of the cited passage fails to reveal any such disclosure:

FIG. 3 shows that sequences juxtaposed to the TCR delta locus in the translocation chromosome of t(1:14) map to chromosome 1. DNA (10 μg/lane) from the following sources was digested with an excess of restriction enzyme Hind III, electrophoresed, transferred to a nitrocellulose filter, and hybridized with the p528H5:1 probe (see FIG. 2): mouse LMTK- cell line(lane 1); M44c12S5 hybrid retaining the 14q+ chromosome from the translocation t(8;14)(q24;q32) (lane 2); GL5 hybrid retaining chromosome 4, 13, 14, 18, 20, 21, X and partial chromosomes 17 and 22 (lane 3); 401 AD5EF3 hybrid retaining partial 8 and 22 and chromosomes 19, 21, and X (lane 4); 42-63c17-17 hybrid retaining the 14q+ chromosome from the translocation t(14;X)(q32;q13) (lane 5); GM7299 hybrid retaining chromosomes 1, 6, and X (lane 6); human placenta (lane 7); PB5 hybrid retaining partial chromosomes 1, 2, 3, 5 and 17 (lane 8).

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Applicants concede that this passage from the Croce patent mentions chromosomes 3 and 17. However, it does not, as the Examiner suggests, disclose "chromosome 3 and 17 translocation targets." The Croce patent is directed to "molecular methods of identifying certain chromosomal abnormalities involving human chromosome 1 band p32." The passage from the Croce patent cited by the Examiner is a description of Figure 3. The significance of Croce Figure 3 is given in Example 1. The experiments described in Example 1 are directed towards "the identification of the t(1;14)(p32;q11) chromosomal breakpoint in leukemic cells." (col 6, lines 42-44). The only direct reference to Figure 3, other than that cited by the Examiner, appears at col 7, lines 44-49 of Example 1:

Probe p528H5.1 was hybridized to a Southern filter with bound DNA from rodent×human hybrid cells containing either human chromosome 1 or human chromosome 14. The presence in the hybrids of the 5.1 kb HindIII fragment correlates only with the presence of human chromosome 1 (FIG. 3), demonstrating that we have cloned the t(1;14) breakpoint on the DU.528 1p+ chromosome (1qter->1p32::14q11->14qter).

That is, although DNA from chromosomes 3 and 17 were used in the test, the only chromosomes to which the probes bound were chromosomes 1 and 14, indicating translocation targets on chromosomes 1 and 14, not on chromosomes 3 and 17. It is well-settled that it is impermissible within the framework of 35 U.S.C. §103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art. *Bausch & Lomb, Inc. v.* 

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Barnes-Hind/Hydrocurve, Inc. 230 USPQ 4126 (Fed. Cir. 1986). A full appreciation of the Croce patent fairly suggests that it does not disclose what the Examiner suggests it does. Consequently, the presently claimed invention cannot properly be held to be *prima facie* obvious over Weissman in view of Lichter and Croce. Withdrawal of this rejection is thus respectfully requested.

Further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this response, or to the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

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